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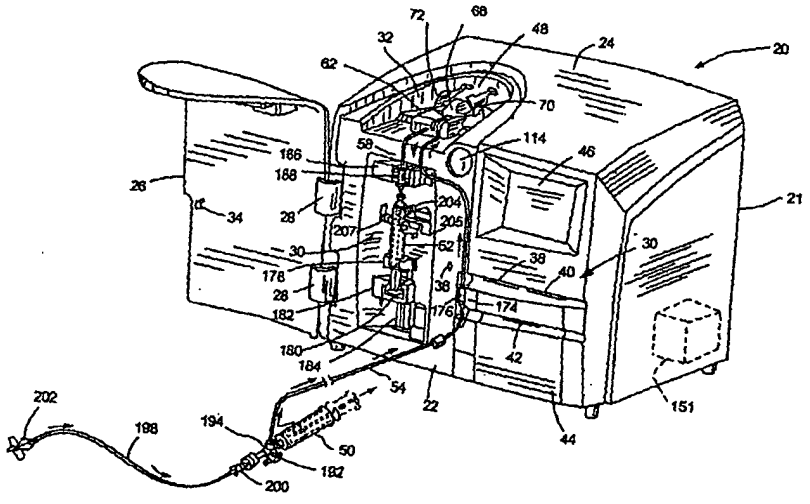
(54) Title: NEEDLE ASSEMBLY AND HEAT SEALER FOR PATIENT INJECTION APPARATUS AND PROCESS



(57) Abstract: The invention provides a double ended injection needle assembly, e.g. for injecting conditioning organic fluid to a patient in a medical procedure. The apparatus includes a needle hub wherein a first end of the needle may be inserted intramuscularly while a second end of the needle projects beyond the patient's tissue and the second end being shielded. The apparatus also includes a heat sealing device for a thermoplastic medical tubing, thereby providing a sealed and closed batch system for treatment of the charge and thus reducing the risk of contamination of the charge, reducing the risk of cross contamination between charges, and reducing the risk of the charge contacting the operator.

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NEEDLE ASSEMBLY AND HEAT SEALER FOR PATIENT INJECTION APPARATUS AND PROCESS

FIELD OF THE INVENTION

This invention relates to sealing and injecting systems for use with medical injection apparatus. More specifically it relates to such systems which will provide a substantially sealed system thereby reducing the risk of contamination.

BACKGROUND OF THE INVENTION

Various treatments have been proposed for the treatment of mammalian blood *ex vivo* to condition the blood in some way before injecting the blood into a patient. Some procedures take blood from a patient, condition the blood, and then return the blood to the same patient continuously. These procedures contrast with procedures which require that the blood be taken from the patient to be treated as a batch and then returned to the patient. In batch processes there is the possibility that the blood will be given to the wrong patient as well as the dangers inherent in transferring blood from one location to another. Also, batch treatments are potentially hazardous because of the risk of blood contamination during the process of conditioning the blood, because of the risk for cross contamination between batches, and also because of the potential for infecting the operator accidentally.

A blood treatment process using batch treatment techniques involves three main steps. Firstly, the blood is sourced either from a donor or from a patient, who will also be the patient receiving the conditioned blood. The blood may be mixed with an anticoagulant and the blood charge must then be transferred to apparatus used to condition the charge. In a second step, the blood is conditioned. Finally, in a third step, the conditioned charge has to be collected and prepared for injection into the patient. These steps may involve the use of needles (sharps), tubing, valves, syringes and ancillary parts and connectors. At every stage it is important to minimize risk so that the charge is

moved and treated without contamination, and so that none of the charge comes into contact with the operator running the procedure and so that none of the charge comes into contact with non-disposable parts of the apparatus.

Also in connection with such processes, and in other cases where a patient is to be given multiple successive injections at the same site and during the same treatment session, it is often desirable to accomplish the injections with a single needle, left in place during the injections. This reduces contamination risks, and eliminates the patient's discomfort of multiple punctures. An example is a situation where intramuscular injection is being undertaken, requiring an initial injection of local anaesthetic followed by injection of biological fluid to the same precise site.

It is an object of the present invention to provide a novel injection needle assembly to address these problems.

It is another object of the present invention to provide a heat sealing method and apparatus for thermoplastic medical tubing, for incorporation into a biological fluid treatment system to reduce the risk of contamination of the fluid.

SUMMARY OF THE INVENTION

In accordance with one aspect of the present invention, a closed system for removing a organic fluid from a patient, conditioning the organic fluid, and returning the organic fluid to the patient is described. The system includes an apparatus for removing the organic fluid from the patient, a container for receiving the removed organic fluid, a cabinet for conditioning the organic fluid in the container, and an apparatus for delivering the conditioned organic fluid to the patient, wherein the system prevents contamination between removal of the organic fluid from the patient and delivery of the organic fluid back to the patient.

In accordance with another aspect of the present invention, an apparatus for conditioning of a organic fluid includes a cabinet for conditioning the organic fluid, an input system, and an output system. The output system including a syringe for receiving said organic fluid from said output port of said

container, wherein an output tube connects said output port to said syringe, the output system further including a heat sealing device disposed between said output port and said syringe for substantially severing and sealing said tubing.

Thus the present invention provides a needle assembly for injecting a patient successively with a plurality of fluids, comprising:

a needle having a sharp distal end for injection into a patient, and a proximal end in fluid communication with the distal end;

a chamber attached to the needle, surrounding and protecting the proximal end of the needle, the distal end of the needle protruding beyond the chamber;

characterized in that said chamber is adapted to removably connect to a container of biological fluid whereby, upon said connection, the proximal end of the needle receives biological fluid from the container.

In accordance with a further aspect of the present invention, a method for removing a organic fluid from a patient, conditioning the organic fluid, and returning the organic fluid to the patient without contamination includes the steps of:

removing the organic fluid from the patient;

receiving the removed organic fluid in a container;

conditioning the organic fluid in the container; and

delivering the conditioned organic fluid to the patient, wherein contamination of the organic fluid, contamination of the conditioning apparatus, and contamination of the operator are prevented between removal of the organic fluid from the patient and delivery of the organic fluid back to the patient.

In yet another embodiment there is provided a method and device for heat sealing medical tubing, thereby preventing contamination of the fluid within the tubing, potential contamination to an operator, or contamination of reusable parts of the device. In addition, there is provided a device for shielding the non-sterilized heat sealed tubing ends thereby protecting the operator from contamination from the non-sterile surfaces.

In accordance with another aspect of the present invention, a needle assembly for delivering or removing multiple fluids includes a needle device and a first fluid delivery or removal assembly. The needle device includes a first body having a needle with a first tissue penetrating end, a second fluid receiving end in fluid communication with the first tissue penetrating end, and a chamber which surrounds the second end. The first fluid delivery or removal assembly has a fluid chamber and is configured to be received in the chamber of the needle device with the second end penetrating into the fluid chamber.

BRIEF DESCRIPTION OF THE DRAWING FIGURES

There will now be described preferred embodiments of the invention, with reference to the drawings, by way of illustration, in which like numerals denote like elements and in which:

Figure 1 is an isometric view of apparatus used in practicing a process of conditioning blood charges in accordance with a preferred embodiment of the invention and including a cabinet;

Figure 2 is an isometric view of a disposable container assembly adapted for use with the apparatus;

Figure 3 is an exploded view of the needle assembly of the present invention;

Figure 4 is a cross-sectional view illustrating the needle assembly prior to assembly for use;

Figure 5 is a cross-sectional view illustrating the needle assembly as assembled for use;

Figure 6 is a perspective view of one embodiment of the heat sealing device of the present invention;

Figure 7 is a cross-sectional top view of the heat sealing device of Figure 6;

Figure 8 is an enlarged cross-sectional top view of the heat sealing device of Figure 6 having the heat sealing jaws in an advanced position;

Figure 9 is an exploded view showing the separation of the tubing and locator device after heat sealing with the heat sealing device of Figure 6;

Figure 10 is a perspective view of another embodiment of the heat sealing device;

Figure 11 is a cross-sectional view of the embodiment of the heat sealing device of Figure 10;

Figure 12A is a cross-sectional view illustrating the heat sealing jaws of Figure 10 advanced into a sealing position;

Figure 12B is a cross-sectional view illustrating the heat sealing jaws of Figure 10 retracted from the sealing position after sealing the tubing;

Figure 13 is a cross-sectional view illustrating the separation of the tubing after heat sealing with the heat sealing device of Figure 10; and

Figure 14 is a perspective view illustrating the separation of the locator device after the tubing has been heat sealed with the heat sealing device of Figure 10.

DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

As seen in Figure 1, apparatus with which the present invention may be used in a preferred embodiment, designated generally by the numeral 20, includes a cabinet 21 having a front 22 and an inclined top 24. A hinged door 26 is attached to the cabinet 21 to one side of the front to move about vertical hinges 28 between an open position shown in Figure 1, and a closed position (not shown) where it covers a front recess 30 and a top depression 32. The door is equipped with a locking bar 34 which engages in a recess 36 where it can be retained to hold the door in the closed and locked position to create a secure environment inside the cabinet 21.

The cabinet 21 is designed to be secure while the charge is being conditioned. The apparatus 20 includes an identification system so that the apparatus 20 can be used by an operator only after a patient has been designated and identified by the apparatus by way of a discrete smart card (not shown) which has to be inserted by the patient or operator in a first slot 38. A second smart card or operator's smart card is inserted by the operator in a

second slot 40. The patient keeps the patient's smart card or the card is attached to the patient by a locking bracelet so that the apparatus can be used only by the operator in the presence of the patient until the apparatus is ready to treat another charge. The smart cards can be used to store data developed during operation of the apparatus and can become a permanent record of the procedure. A third slot 42 in a printer door 44 will produce a printed record of the treatment as required.

According to alternative embodiments of the invention, the smart cards may be replaced by other readable identifiers, such as tokens, keys, bar codes, or other systems. In addition, the two smart cards may both be received in a single slot in the apparatus 20 or the operator card may be omitted.

The operator controls the apparatus using a graphical display terminal (GDT) 46 having a touch screen interface pad overlaid on the GDT. The GDT serves to interrogate the operator to ensure that every required step is completed in the required sequence. Errors and instructions are also available on the GDT. Although a GDT and touch screen has been described, other operator interfaces can also be used.

As mentioned, the door 26 can be moved into a locked and closed position to cover the front recess 30 and the top depression 32. In the position shown in Figure 1, a sterile container assembly, designated generally by the numeral 48, has been lowered into the cabinet such that part of the assembly 48 can be seen projecting upwardly into the depression 32. An input syringe 50, and an output syringe 52 have been removed from the assembly 48 ready for use. The input syringe 50 is used to source a charge and pass the charge through thermoplastic inlet tubing 54 to a container 56 which can be seen in Figure 2. After treatment in the container 56, the conditioned charge is drawn through outlet tubing 58 from the container 56 into the syringe 52 by an actuator 182.

The sterile container assembly is preferably a disposable assembly used for only a single patient to prevent charge contamination, cross-contamination between charges, or operator contamination. The term container as used herein is intended to include any container configured to

receive a charge for treatment, such as a flask. The container may be rigid or flexible, such as a container in the form of a flexible bag.

The term contamination as used herein is intended to include any one or more of the following a) contamination of the charge from an exterior environment; b) contamination of the reusable parts of the treatment apparatus which may result in cross contamination between charges of different batches; c) contamination of the operator; and d) contamination of the exterior environment from a charge.

There are three stages to the treatment. Firstly, the charge is sourced and passed by syringe 50 to the container 56 (Figure 2). Next, treatment takes place in the container 56 and then the conditioned charge is drawn automatically from the container into the output syringe 52 ready for injection into the patient. All of these steps are controlled by the apparatus 20 in such a way that there is a limited risk of contamination. The risk of contamination is substantially eliminated by the elements of the system which will be described herein including the heat sealing of the charge carrying tubes and the needle assembly. Further the patient is identified by the identification system in such a way that if the charge is sourced from the patient for subsequent return to that patient, the treated charge will be available only when the patient presents his/her smart card to thereby ensure that the right patient gets the charge.

Figure 2 shows describe the main features of the container assembly 48 as it would appear in a sterile condition ready for placement in the cabinet 21 (Figure 1). The container assembly 48 will be supplied in a sterile container which may also include most of the items needed for the procedure. These may include needles, tubing, gauze etc. as is commonly done in medical procedures requiring sterile items for the procedure.

The assembly 48 is made up of two main parts, namely the container 56 and a connector assembly 62 which serves to carry components used in the treatment procedure. The assembly 48 is shown as it would be placed in the cabinet 21 (Figure 1), with the input syringe 50 and output syringe 52 mounted side-by-side on the connector assembly 62. It will be seen that the

connector assembly includes an overhanging portion 64 which will meet parts of the apparatus contained in the cabinet 21 when the container assembly 48 is lowered downwardly into the cabinet 21. As will be described, electrical and gas connections are made automatically when the assembly 48 moves into its final position in the cabinet 21. Also, the overhanging portion 64 provides clearance under the portion 64 to allow the inlet tubing 54 to be fed from the input syringe 50 to a supply probe 65.

The syringes 50 and 52 are conveniently stored on the connector assembly 62 between a central shaped mound 66 (Figure 1) and respective locators 68 and 70 which are sufficiently flexible to allow the syringes to be engaged and held in place. Further location is provided by respective channel portions 72, 74 which receive respective flanges 76, 78 on the syringes 50 and 52. This interengagement locates the syringes 50, 52 longitudinally but does not interfere with vertical removal of the syringes 50, 52.

The container assembly 48 is located in the cabinet 21 by convenient, conventional mounting means. The cabinet also contains stressor delivery means such as an IR heater undr thecontainer and UV lamps around the sides of the container.

Figure 2 also shows the shape of the container 56. It extends about a longitudinal axis 89 and has a generally cylindrical main portion 90. A transitional portion 92 extends from the portion 90 to a cup 94 proportioned to receive about 12 ccs of charge from the input syringe 50 (Figure 1).

The container 56 according to one embodiment of the invention is essentially an envelope made by blow molding a parison of low density polyethylene (LDPE) and has an internal volume that is about 70-100 times that of the charge. The walls are translucent to allow penetration of the UV and IR light stressors.

The container assembly 48 then receives the syringe locators 68 and 70 which snap into respective slots 168, 170 formed in the top of the cover 158. The outlet tubing 58 is then fed through an opening 172 at the back of the cover 158 and attached to the syringe 52. Similarly, the inlet tubing 54 is attached to the syringe 50 and the syringes are engaged on the cover 158 to be

held in place (as previously described) by the combinations of the mound 66 with the respective locators 68 and 70.

The main structural features of a type of apparatus to which the double needle assembly and heat sealing device of the present invention may be applied have been described. Further detail, if required, of this general type of apparatus may be had by reference to applicant's companion application PCT/CA00/01078 (publication number WO 01/19718), which describes such an apparatus in more detail. It is incorporated herein by reference in its entirety.

The process in general is designed to source suitable organic fluid either by using compatible blood or by using blood taken from a patient who is to receive the treated blood. This process will be described for the latter case but is not to be limited to that case.

The apparatus must be readied for use by placing the operator's smart card in the slot 40. A patient's smart card comes with the package containing the container assembly 48 and the operator or patient places the patient's card in the slot 38. The GDT 46 then proceeds to present instruction, error messages, and comments as the procedure progresses.

Once this is done, the door 26 is unlocked by the control circuit, and a new container assembly 46 is removed from its sterile package and lowered into a cavity in the cabinet to take up the position shown in Figure 1. At this point the syringes 50, 52 are in place on the connector assembly 62, as shown in Figure 2.

Next the input syringe 50 is lifted from its position on the connector assembly 62 and placed conveniently with the inlet tubing 54 passing through a heat sealing device 174 which is attached to the cabinet 21 for use to seal and substantially sever the inlet tubing 54 as will be explained. The inlet tubing 54 has a locator 176 mounted on the tubing to position the inlet tubing 54 in the device 174.

The output syringe 52 is then removed in similar fashion and placed vertically as shown in Figure 1. The syringe 52 is located in a fixed mount 178 using the flange 78 and a syringe operator 180 extends downwardly and is engaged in an actuator 182 which can be driven along a slide 184 by a

motor and drive (not shown) in the cabinet. This operation will be described with reference to removing a conditioned charge.

The outlet tubing 58 associated with the syringe 52 is led through a second heat sealing device 186. The heat sealing device 186 includes a locating body 705 positioned on the tubing 58 which positions the outlet tubing between jaws of the heat sealing device 186. This device 186 will be used after the conditioned charge is drawn into the syringe 52, as will be explained.

A message on the GDT 46 (Figure 1) reminds the operator to close the door 26 and the door lock bar 34 is engaged. The control system 151 (Figure 1) activates the door so that the cabinet can be opened only by using the two smart cards. Consequently the smart card carried by the patient is necessary so that no one other than the patient can cooperate with the operator to get into the cabinet 21. The patient's smart card is preferably attached to the patient's wrist in a semi-permanent fashion using a suitable band of the type commonly used in hospitals.

The input syringe 50 is still in the condition shown in Figure 2. A T-connector 190 includes a valve controlled by a selector 192 which connects the body of the syringe to either an in-line port 194, or a side port 196 at right angles to the axis of the body. The inlet tubing 54 is attached to the port 196 and the port 194 is available. The input syringe 50 and the associated parts are then moved to the position shown in Figure 1.

A needle (not shown) is attached to port 194 and about 2 ccs of an anticoagulant (preferably sodium citrate) is drawn into the syringe. The needle is discarded into a sharps container and then a tubing assembly 198 (Figure 1) is attached to the in-line port 194. This assembly 198 includes a one-way valve 200, to avoid back flow, and at its leading end an angel wing collector set 202 is ready for engagement into the patient to collect blood. The collector set is used to draw 10 ccs of blood into the syringe 50 where it is mixed with the sodium citrate by rocking the syringe gently to create a blood charge for treatment in the process according to the invention.

Next, the selector 192 on the T-connector 190 is operated to connect the body of the syringe 50 with the side port 196 leaving the tubing

assembly attached but inoperable. The syringe 50 is then inverted (i.e. placed with the T-connector uppermost) and about 3 to 4 ccs of sterile air are drawn from the container 56 into the syringe. The syringe 50 is then again inverted so that the air is above the charge and the syringe is then operated to drive the charge through the inlet tubing 54 and into the container 56 driven by the air in the syringe. As a result the inlet tubing is cleaned out as the air follows the charge.

After the input syringe 50 and associated parts have been used to deliver the charge to the container 56, they can be discarded. Before this can be done, the syringe 50 has to be separated from the cabinet 21 to which it is connected by the inlet tubing 54. This is achieved by operating the heat sealing device 174 which seals and substantially severs the tubing under the influence of heat. The structure and operation of heat sealing devices will be described in further detail below with reference to Figures 6 - 14.

It should be noted that the door 26 (Figure 1) has not been opened during this procedure and that the charge of blood and sodium citrate has been received in the cup 94 of the container 56 (Figure 3). It should be noted that although the process is to condition blood, to be accurate the process treats blood as the prime part of a charge which also contains an anticoagulant, (or any other additive). Consequently the term "charge" is used to describe a batch made up of blood and at least one additive. However if circumstances arise in which blood can be treated alone, such use is within the scope of the term because organic fluid continues to be the subject of the treatment and it is not intended to exclude such an interpretation. Although the term fluid has been used herein, it is expected that primarily liquids will be treated with the apparatus of the present invention.

When the conditioning is complete the apparatus will commence the step of moving the charge from the container 56 to the output syringe 52. This is done automatically by the actuator 182 seen in Figure 1, which draws the operator 180 downwardly. When all the fluid has been withdrawn from the container 56 into the syringe 52, considerable amounts of gas are aspirated therein. In the case of foaming liquids, such as blood, the air is contained in

persistent bubbles which do not settle rapidly and must be removed. To this end, a knocker 204 is disposed adjacent to the syringe 58 whose purpose is to apply sudden accelerations to the syringe. For best effect, the syringe 58 is constrained radially only very loosely through the use of soft elastomeric supports, such as a coil spring 207. According to one example, the syringe can translate 8 mm with less than 1 N force applied by an impact tool 205. The effect of the sharp shocks delivered by the knocker 204, is to rapidly accelerate the syringe barrel radially. The inertia of the fluid film in the bubbles causes their structure to be disturbed by the rapidly moving walls and one observes a general collapse of the bubbles after a number of shocks have been delivered.

Although any impulse delivering electro-mechanical system will perform the function of the knocker 204, one preferred embodiment includes a rotary impact tool 205 positioned on a rotating arm. An elbow of the rotating arm is provided with a torsion spring and the hand of the arm is provided with a roller. The device rotates in a volute or spiral cavity so that as the arm rotates, energy is stored in the torsion spring until a release point is reached and the arm rapidly deploys its energy in impacting the syringe 58. The frequency of the knocker 204 can be varied and will to some extent depend on the geometry and mass of the parts. However, it has been found that a frequency of 1 Hertz provides good results.

Next the actuator 182 is operated to express some of the contents of the syringe 52 back into the outlet tubing 58 until there remains a volume of 9 to 10 ccs of conditioned charge. A sensor (not shown) in the heat sealing device 186 tells the control system in the cabinet 21 that the system is ready to seal the outlet tubing 58 in similar fashion to the seal made on the inlet tubing 54 as previously described.

Referring now to Figures 6 - 9 there is shown one embodiment of the heat sealing device 186. The heat sealing device 186 includes a locating body 705 positioned on a tubing 58 and first and second heat sealing jaws 710. The locating body 705 is comprised of a first body 720 and a second body 730 wherein the inner bore 732 of the second body 730 is adapted to receive the first body 720. The first and second bodies 720, 730 each include two

apertures 707 adapted to receive the sealing ends 712 of the first and second heat sealing jaws 710. The first and second bodies 720,730 respectively, further include apertures 721,731 respectively for receiving the medical tubing 58. The locating body 705 is preferably a disposable element connected to the medical tubing.

The heat sealing jaws 710 may be formed of steel, stainless steel, titanium, copper, brass, Nitinol, ceramic or similar materials which have good heat conductive properties. In one embodiment, the jaws 710 are formed of copper having resistive heating wire, such as Nichrome wire, wrapped thereabout. Thus in use, a current is applied to the Nichrome wire, thereby generating heat which is conductively transferred to the copper jaws 710. Alternatively, the jaws 710 may include a firerod (not shown) disposed within a bore, wherein a current is passed through the firerod thereby generating heat which is conductively transferred to the jaws 710. In another embodiment, a transistor may be used to heat each of the jaws 710. If a transistor is used for heating, the transistor may also be used to measure the temperature of the jaws. The heat sealing jaws 710 are attached to appropriate supporting, guiding, and advancing means (not shown).

Referring now to Figure 7 there is shown a cross-sectional view of the heat sealing device 186 wherein the first body 720 is disposed within the bore of the second body 730 and the tubing 58 passes through the apertures 721 and 731. The proximal ends 712 of the heat sealing jaws 710 are advanced as shown in Figure 8 until they contact the tubing 58. After contacting the tubing 58 the jaws 710 are advanced until the proximal ends 712 touch or nearly touch. Prior to or during the process of advancing the jaws, the jaws 710 are heated. A protruding rib 716 on each of the jaws 710 substantially severs the tubing 58. Thus, the tubing 58 is pinched, sealed, and substantially severed by the hot jaws 710. The jaws 710 are then cooled and retracted from the apertures 707. The jaws 710 should preferably be held in contact with the tubing 58 until the tubing has cooled from a molten to a solid state to form a seal on the two substantially severed ends of the tubing.

Referring now to Figure 9 there is shown the first body 720 and the second body 730 as disassembled after sealing. As illustrated, the tubing 52 is fixedly attached at the apertures 721, 731 to the first body 720 or second body 730 respectively. Therefore, when the tubing 52 is removed from the apparatus 20, the substantially severed, heat sealed ends are protected by the first body 720 or second body 730, respectively. Because the ends are covered and protected from handling there is a lesser likelihood of contaminating the operator or contaminating the apparatus 20.

As shown in Figure 6, the heat sealing device 186 may further include a location means 500. The location means 500 includes a recessed region 510 adapted to receive the projection 735 or 725 disposed on the first body 720 or the second body 730. The location means 500 provides a simple and effective method of holding and aligning the locating body 705 within the device 20. Additionally, the heat sealing process described above requires that the jaws 710 be in contact with the tubing 58 for a period of time, thus, the location means 500 provides support and alignment of the locating body 705 thereby allowing heat sealing of the tubing 58. The location means 500 may be formed of a plastic, metal or other material. The location means 500 is preferably integrally formed with the device 20. Preferably, the jaws 710 are sterilized between uses. One example of sterilization would be heating the jaws 710 in place in the apparatus 20 to about 140 degrees Celsius for about 4 minutes.

Referring now to Figures 10-14 there is shown a second embodiment of a heat sealing device 186'. The heat sealing device 186' includes a locating device affixed to a tubing 58, shown in Figures 10 and 11, and heat sealing jaws 860 for sealing the tubing as shown in Figures 12A and 12B. The locating device shown in Figure 10 includes a first body 810 having an aperture 812 disposed through a proximal end and a second body 820 having an aperture 822 disposed through a proximal end. The second body 820 is adapted to be received by an inner bore of the first body 810. The second body 820 includes a flange 825, which abuts the distal end of the first

body 810 when the first and second bodies are assembled together as shown in Figures 10 and 11.

As shown in Figures 10 and 11 the first body 810 may be formed having a "U" shape with a foil covering 830 disposed on either side thereof. The foil 830 may be any ductile foil suitable for heating and able to act as a sterile barrier. One example of a suitable foil is a ductile aluminum foil laminate. Other barrier materials may also be used and may be secure to the first body 810 in any known manner. The second body 820 may be formed having a rectangular shape including the flange 825 disposed at the proximal end and a tubing guide 827 disposed at the distal end. As shown, the tubing 58 passes through the aperture 812 where the tubing is fixedly attached to the first body 810 with a compatible adhesive, and similarly attached to tubing guide 827 on the distal end of the second body 820. The tubing 58 and guide 827 are able to slide through the aperture 821 of the second body 820.

Referring now to Figures 12A and 12B there is shown the heat sealing device 186' in use. A pair of pre-heated jaws 860 are advanced as shown in Figure 12A, the distal tips 861 of the jaws 860 are designed to converge along a line. The tubing 58 is compressed between the jaws and heat is conducted from the jaws to the tubing through the foil 830. As shown in Figure 12B, the tubing 58 is pinched, sealed, and substantially severed by the hot jaws 860. The foils 830 serve as a barrier between the contaminated tube ends and the heat seal jaws. An advantage of the present embodiment of the heat sealer is that the jaws 860 do not contact the tubing 58 and the foil 830 provides a sterile barrier. This prevents contamination of the jaws.

In addition, the ductile foil deforms to support the molten seal zone of the tube so that the hot jaws can be withdrawn and the tube ends allowed to cool rapidly without changing shape. The use of aluminum foil allows for good cooling but other methods of cooling may also be used. Alternatively, the foils 830 may be replaced by other barriers, such as formed plastic shields which snap into stops as the tube is compressed between the jaws.

As shown in Figure 13, after the tubing 58 has been pinched, sealed and substantially severed, the section of tubing 58 disposed through the

tubing guide 827 is retracted. The tubing 58 is retracted until the tubing guide 827 rests against the proximal end of the bore 823 adjacent to the flange 825. The heat sealed end of the tubing 58 is held in this retracted position by friction or other appropriate means. After the tubing guide 827 contacts the flange 825, further force applied to the tubing 58 will cause the second body 820 to slide out of the bore 811 as illustrated in Figure 14. The walls 828 of the second body 820 protect the heat sealed end 57 of the tubing 58, thereby preventing an operator from touching the non-sterilized tubing.

Although the geometry of the first body 810 and the second body 820 have been shown and described in relation to the specific geometries illustrated this should not be considered limiting in any manner. The bodies defining the overall geometric shape may be formed in any manner. In addition, although two heat sealing jaws have been shown, it is also possible to use a single heat sealing jaw and an anvil to perform severing and sealing.

After the heat sealing device has sealed the outlet tubing 58 the process has now reached a critical point. If the patient or operator has not inserted the patient's smart card by now, the apparatus will wait only for a predetermined time (usually about 20 minutes) before aborting the process. If the process is to be aborted, a message will appear on the GDT 46 (Figure 1) and the control system will cause the actuator 182 to drive the syringe operator 180 so that the conditioned charge is returned to the container 56 before shutting down the process. The heat sealer then seals the tube 58 to prevent accidental use. Once this is done the operator can open the door 26 using only the operator's card so that the container 56 and its contents can be discarded to ready the apparatus 20 for a new process.

If the patient presents the patient's card in time, the respective smart cards are inserted into the slots 38, 40 and the heat sealer 186 will seal and substantially sever the tubing 58, the door 26 will open, and the output syringe 52 is then available for removal from the cabinet 21. However, before this is done, the patient must be prepared for the injection of about 8 to 9 ccs of conditioned charge. Firstly, the patient is anaesthetized in the gluteus maximus muscle using a suitable needle and performing the standard procedure for

ensuring that the needle has not been inserted into a vein. Next, the anesthetic syringe is removed and the needle is left in the patient. The output syringe 52 is fitted with the same type of hub fitting as the anesthetic syringe. The output syringe 52 is then taken to the anesthetic needle and after discarding the remaining tubing 58 from the heat sealing operation, the output syringe 52 is attached to the anesthetic needle and the conditioned charge is fed into the patient slowly. After this procedure, the output syringe and attached needle are discarded.

The apparatus can then be prepared for the next procedure by removing the remains of the container assembly 48.

It will now be evident that the process can be used to treat mammalian blood in a blood charge to provide a conditioned charge for giving to a patient in a medical procedure. In general the process includes the steps of providing an automatic apparatus for treating the blood charge to create the conditioned charge, and for presenting the conditioned charge ready for use. The apparatus has a secure environment, a door controlling access to the environment, a container, and stressors arranged to operate on a charge in the container in the controlled environment. The blood charge is transported into the secure environment through thermoplastic inlet tubing for deposit in the container, and the tubing is then sealed and substantially severed. Next the part of the inlet tubing outside the secure environment is removed and the operation of the automatic apparatus is initiated so that the stressors will operate on the charge for a predetermined period, thereby stressing the charge in the container while maintaining the secure environment. The apparatus is then given time to transport the conditioned charge from the container to a receiver, and the door is opened to provide access to the receiver for use to give the conditioned charge to the patient.

Improved control can be provided by the preferred use of smart cards, as explained, and by the use of thermoplastic tubing and heat sealers to ensure that the secure environment is maintained. Also, the process can be enhanced by use of the knocker to reduce the time needed to dissipate the bubbles in the conditioned charge.

Referring now to Figures 3-5 there is shown a needle assembly 600 for use with the apparatus and methods of the present invention. After a charge has been prepared according to the process described above, the charge is injected intramuscularly back into the patient's body. Typically, this process is carried out by first injecting the patient with a local anesthetic intramuscularly, such as in the gluteus maximus. After inserting the needle, it is common practice to pull back on the syringe plunger to ensure that the needle is not placed in a vein or artery. Once the anesthetic is injected, the syringe is removed from the needle, thereby leaving the needle in place, the charge prepared above is then attached by a luer fitting (luer slip or luer lock) on the needle and injected. The disadvantage of this method is the potential of contamination to the operator and contamination of the charge when connecting the syringe containing the charge to the needle. In addition, air bubbles may become trapped between the needle and the syringe carrying the charge during connection.

Referring now to Figure 3 there is shown the needle assembly 600 according to the preferred embodiment of the present invention. The needle assembly 600 includes a needle connector 650, a syringe connector 660, and a needle 610. The needle connector 650 includes a proximal end 651, distal end 652, and a handle 654 disposed adjacent the distal end 652. A plurality of walls 653 define a chamber 655. The needle connector 650 and the syringe connector 660 are configured to be connected by a press fit, however, other connections may also be used, such as a snap fit, screw connection or use of other mechanical advantage elements. The needle 610 has a first end 612 adapted to be inserted into tissue and a second end 614 within the chamber 655 adapted to receive the tubing 58.

A plurality of walls 663 define the syringe connector 660. The syringe connector 660 further includes a handle 662, a luer fitting 664, and an aperture 667 disposed through one of the walls 663 wherein the aperture is adapted to receive the tubing 58, which forms in effect a puncturable or penetratable fluid chamber of small dead volume. Other fluid chambers may also be used. As shown in Figure 3, the distal end of a syringe 52 is connected

to the luer fitting 664 of the syringe connector 660. The tubing 58 extending from the syringe is threaded through the interior of the syringe connector 660. The tubing 58 is extended out through an aperture 667. As shown in Figures 3-5, the tubing 58 is disposed within the syringe connector 660 forming a curve 669. Alternatively, the syringe connector 660 may be formed of multiple pieces (not shown) wherein each piece contains a pre-formed area adapted to receive the tubing 58 and retain the curve 669. As shown in Figure 3, the end of the tubing 58 can be heat sealed according to the procedure described above. In one embodiment, the syringe connector 660 can be integrally formed with the heat seal locating body 705.

Referring now to Figures 4 and 5, there is shown the needle 610 of the first body having been inserted into a patient's tissue. A first needle assembly may be disposed within the patient's tissue by first connecting the needle connector 650 to a syringe fitted with a connector for connecting to the needle connector. The syringe connected to the needle connector 650 may be filled with an anesthetic, a beneficial agent, or saline. The needle assembly is then inserted into the patient's tissue, for intramuscular injections, the operator would then pull back on the syringe plunger to ensure that the distal end 612 of the needle 610 did not pierce a vein or artery. In instances where the beneficial agent to be injected is an opaque red fluid, a syringe filled with a clear fluid may be utilized for the initial insertion of the needle so that a "pull-back" test may be performed. After confirming that the needle did not pierce a vein or artery and/or after injection of the anesthetic, the first syringe and associated connector may be removed from the needle connector 650 and a second syringe 52 with the syringe connector 660 may be attached to the needle connector 650.

The walls 653 of the needle connector 650 ensure that the proximal end 614 of the needle 610 is protected thereby preventing finger sticks and contamination during exchange of syringes. As shown in Figure 4, the wall 663 of the syringe connector 660 is received by the chamber 653 of the needle connector 650 so that the distal end 664 of the syringe connector contacts the bottom 652 of the chamber 653 thereby ensuring that the needle will pierce the

tubing 58. The piercing of the tubing with the second end 614 of the needle creates a liquid/liquid interface which prevents possible contamination. Additionally, because the syringe 52 and the tubing 58 contain no air bubbles, the chance of injecting an air bubble during the exchange of syringes is greatly reduced. Also because the syringe assemblies are provided in a sealed condition, the risk of spillage of the contents of the syringes is greatly reduced, therefore reducing the risk of contamination of the contents of the syringe and the risk of contamination to the operator.

The needle connector 650 and the syringe connector 660 may be formed of a bio-compatible material such as urethane, polyvinylchloride, or similar plastics. Additionally the needle assembly 600 may be formed of a clear or opaque material thereby allowing a operator to visually confirm placement of the needle and injection of the beneficial agent. The tubing 58 may be formed of a bio-compatible material such as urethane, silicon, polyvinylchloride (PVC) or preferably polyurethane.

The combination of the needle assembly 600 and the heat sealing device allow the charge to be delivered to the patient without significant risk of contamination. The irreversible steps of the process including heat sealing, puncture of the tubing with the double ended needle for injection, and removal of the smart card from the patient by cutting a locking bracelet may it impossible to incorrectly or inadvertently reuse the disposable elements of the system.

Although the present invention has been described with respect to the treatment of blood, it should be understood that the treatment device may be used for treatment of any biological organic fluid. A biological organic fluid includes but is not limited to the blood, and fractions of blood such as, plasma, red blood cells, white blood cells, immune system cells, antibodies, macrophage, T cells, and B cells.

It will be appreciated that the described embodiments of the apparatus, and of the process associated with the apparatus, can be varied within the scope of the claims and that such variations are within the scope of the invention.

Claims:

1. A needle assembly for injecting a patient successively with a plurality of fluids, comprising:

a needle having a sharp distal end for injection into a patient, and a proximal end in fluid communication with the distal end;

a chamber attached to the needle, surrounding and protecting the proximal end of the needle, the distal end of the needle protruding beyond the chamber;

characterized in that said chamber is adapted to removably connect to a container of biological fluid whereby, upon said connection, the proximal end of the needle receives biological fluid from the container.

2. The needle assembly of claim 1, further characterized in that the proximal end of the needle is sharpened so as to puncture the container of biologically injectable liquid upon connection of the chamber to the container.

3. A syringe and needle assembly comprising:

a fluid container adapted to contain patient-injectable biological liquid, said container comprising a puncturable outlet portion in fluid communication with the container;

a syringe connector comprising walls defining a compartment to envelope the puncturable outlet portion of the syringe, said compartment being open-ended;

a needle connector comprising walls defining a chamber, adapted to fit on an open end of said compartment in substantially contaminant-excluding manner; and

a needle secured to the needle container, said needle having a first sharp end disposed within the chamber and adapted to puncture the puncturable outlet portion of the syringe when the needle connector, the syringe connector and the syringe are fitted together, and a second sharp end

protruding from the needle connector, the first and second ends of the needle being in fluid communication with one another.

4. A closed system for removing a organic fluid from a patient, conditioning the organic fluid, and returning the organic fluid to the patient, the system comprising:

an apparatus for removing the organic fluid from the patient;

a container for receiving the removed organic fluid;

a means for conditioning the organic fluid in the container; and

an apparatus for delivering the conditioned organic fluid to the patient, characterized in that the apparatus for delivering fluid includes a double ended needle device, adapted to receive conditioned fluid from the container at one end, and adapted to deliver said fluid by injection into a patient at the other end, so as to reduce the risk of contamination between conditioning and injection.

5. The system of Claim 4, wherein the apparatus for delivering the conditioned organic fluid to the patient includes a syringe connected to sealed tubing, wherein the sealed tubing is configured to be penetrated by the double ended needle.

6. The system of Claim 4, wherein the apparatus for delivering the conditioned organic fluid to the patient includes a syringe connected to the container by tubing and a heat sealing device arranged to substantially sever and seal the tubing after delivery of the conditioned organic fluid from the container to the syringe.

7. An apparatus for conditioning of a organic fluid, the apparatus including:

a cabinet for conditioning the organic fluid, the cabinet including a container for receiving said organic fluid for conditioning treatment thereof, said container including an input port and an output port;

an input system for transporting said organic fluid through an input tube from a source to said input port of said container, wherein said input tube provides sealed transportation from said fluid source to said input port of said container; and

an output system including a syringe for receiving said organic fluid from said output port of said container, wherein an output tube connects said output port to said syringe, the output system further including a heat sealing device disposed between said output port and said syringe for substantially severing and sealing said tubing.

8. The apparatus according to Claim 7, wherein the heat sealing device comprises:

a first body having a first and second end, a bore extending therethrough, and a second aperture disposed perpendicular to said bore and adjacent said second end,

a second body including a first and second end, a bore extending therethrough, and a second aperture disposed perpendicular to said bore, wherein said bore of second body is adapted to receive said first body, and

at least one heat sealing jaw disposed adjacent said second aperture, and tubing extending through said bore of said first body and said bore of said second body, and wherein said tubing is fixedly attached to said first end of said first body and said second body respectively.

9. Apparatus according to claim 8 including a pair of co-operating heat-sealing jaws moveable towards and away from each other.

10. Apparatus according to claim 9 including a moveable heat sealing jaw and an anvil in co-operation therewith to effect heat sealing.

11. A method for removing a organic fluid from a patient, conditioning the organic fluid, and returning the organic fluid to the patient without contamination, the method comprising:

removing the organic fluid from the patient;
receiving the removed organic fluid in a container;
conditioning the organic fluid in the container; and
delivering the conditioned organic fluid to the patient,
characterized by delivering the conditioned organic fluid from the container to a syringe, sealing a tube between the container and the syringe, and separating the syringe from the container.

12. The method of Claim 11, wherein the organic fluid delivered to the patient is completely contained within a sterile fluid conditioning system between removal of the organic fluid from the patient and delivery of the organic fluid back to the patient.

13. The method of Claim 11, wherein the conditioned organic fluid is delivered to the patient by a double ended needle inserted in a portion of the tube remaining connected to the syringe after sealing.

14. The method of Claim 11, wherein the sealing of the tube between the container and the syringe is performed by a heat sealing device.

15. A heat sealing device for substantially severing and sealing a tube containing a fluid, the heat sealing device comprising:
a first body having a first end, a second end, and a bore extending therethrough for receiving the tube containing fluid;
a second body including a first end, a second end, and a bore extending therethrough for receiving the tube containing fluid, wherein the second end of the first body and the second end of the second body are configured to engage one another; and
at least one heat sealing jaw arranged to substantially sever and seal the tube between the first end of the first body and the first end of the second, wherein the first and second bodies are arranged to separate and

protect first and second substantially severed ends of the tube after the heat sealing jaw has substantially severed and sealed the tube.

16. The heat sealing device of Claim 15, further comprising a flexible foil positioned on the first or second body between the tube and the heat sealing jaw.

17. The heat sealing device of Claim 16, wherein the flexible foil isolates the tube from the two heat sealing jaw before, during, and after a heat sealing process.

18. The heat sealing device of Claim 15, wherein the first and second bodies are cup shaped members arranged to respectively contain the first and second substantially severed ends of the tube.

19. The heat sealing device of Claim 18, further comprising means for sterilizing the two heat sealing jaw by heating.

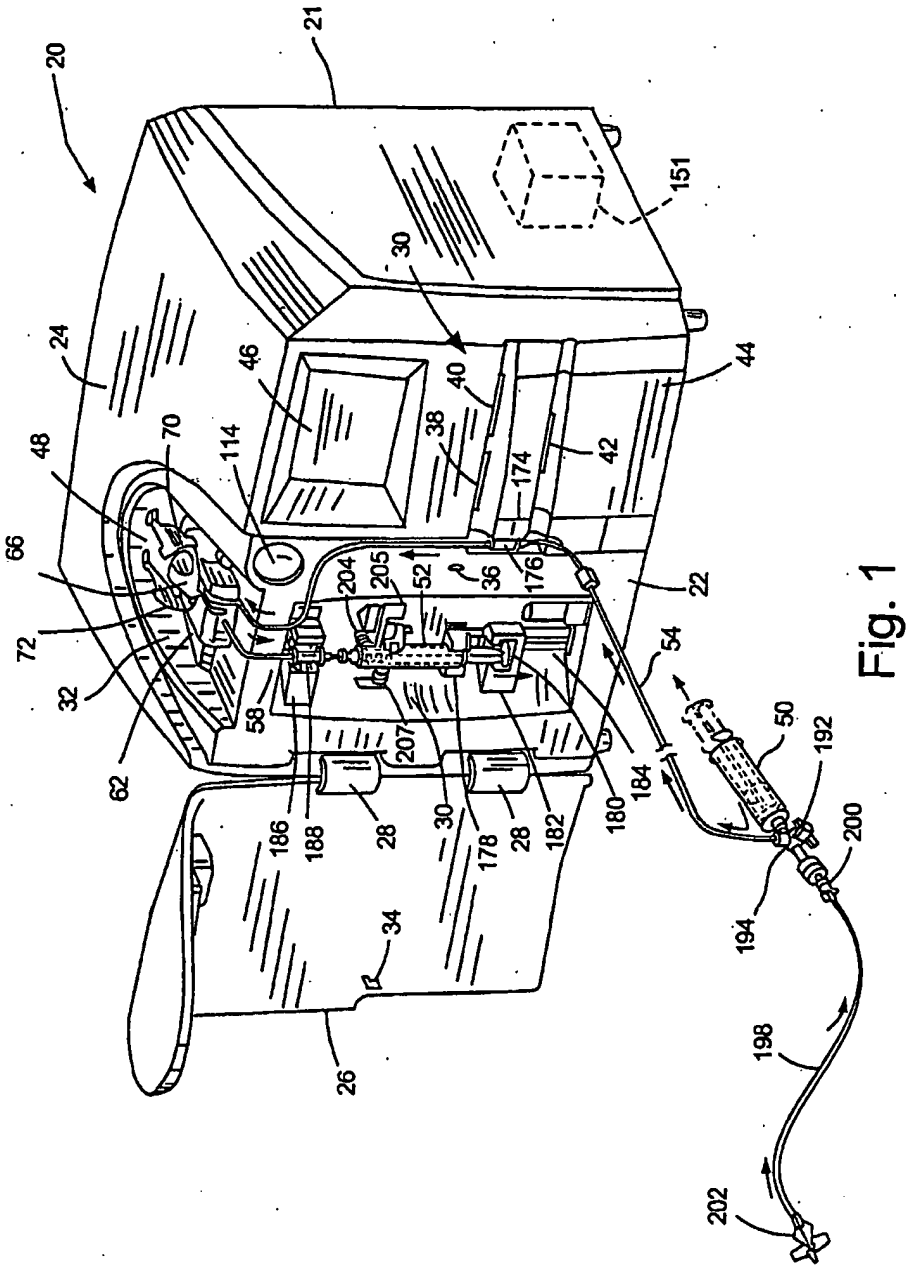
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Fig. 1

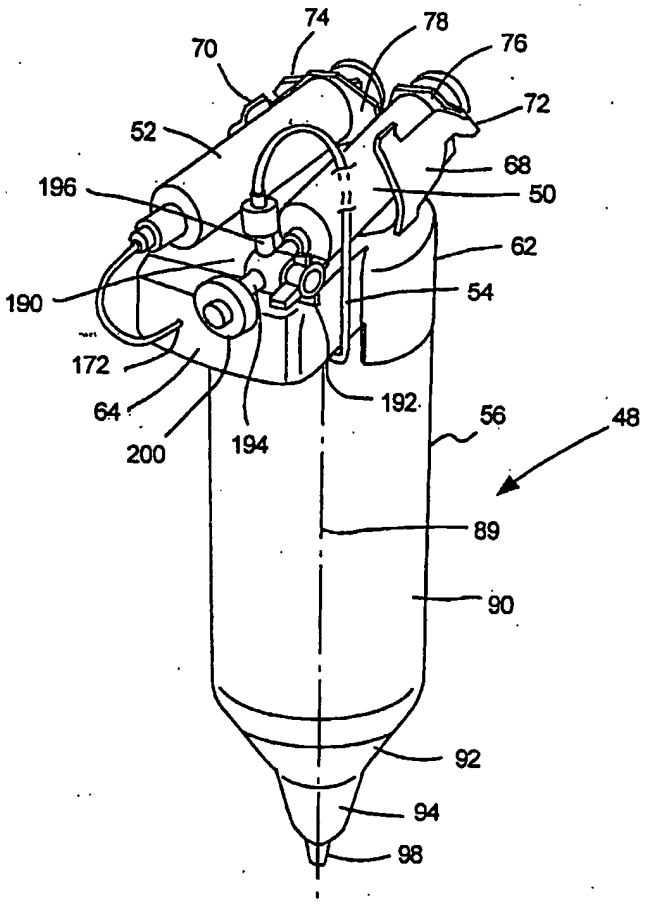
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Fig. 2

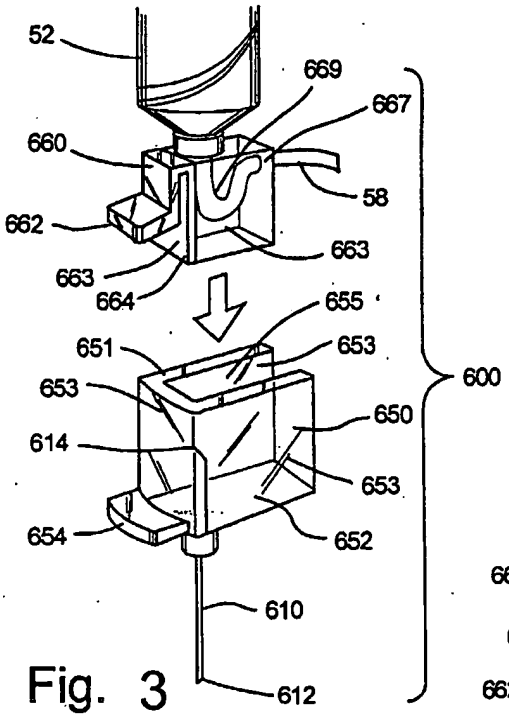

Fig. 3

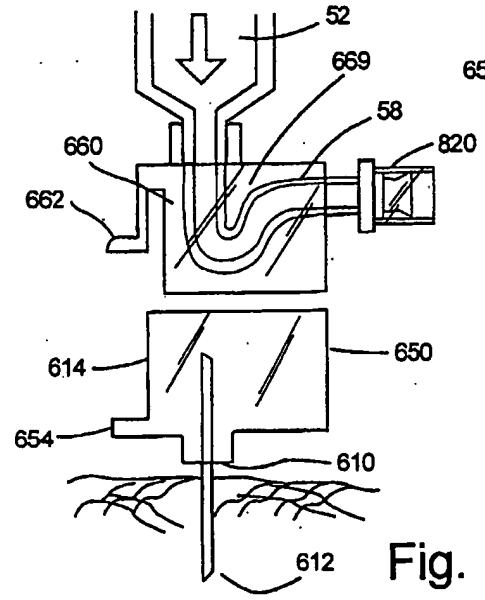

Fig. 4

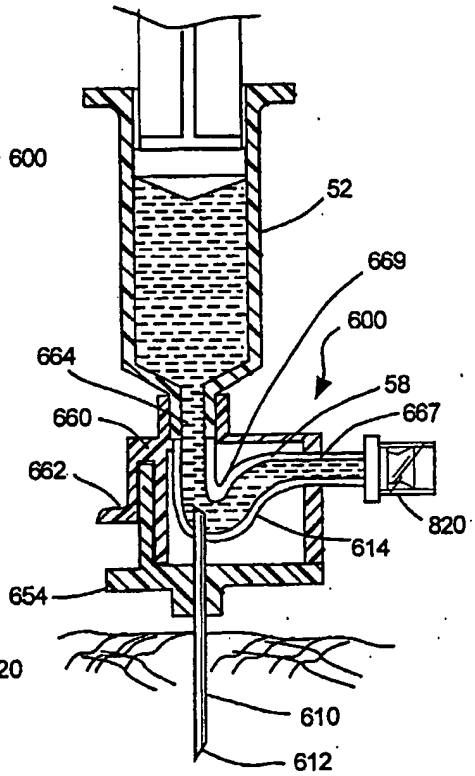

Fig. 5

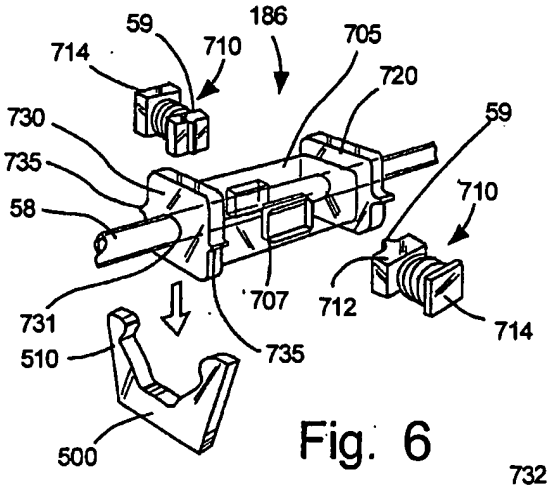

Fig. 6

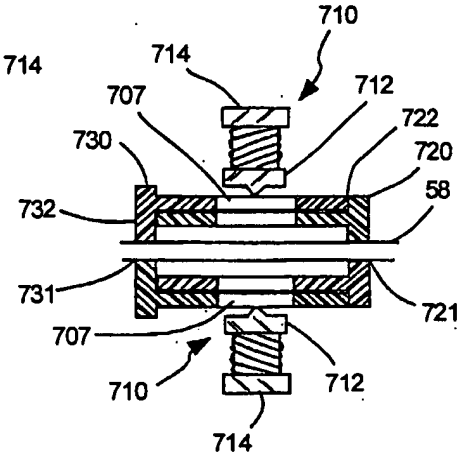

Fig. 7

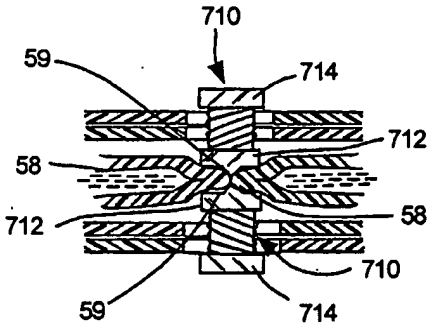

Fig. 8

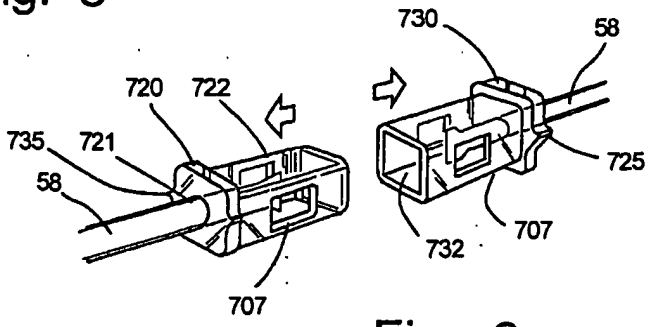

Fig. 9

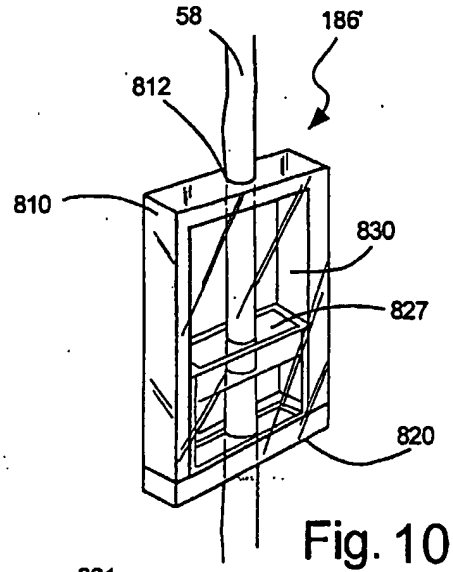

Fig. 10

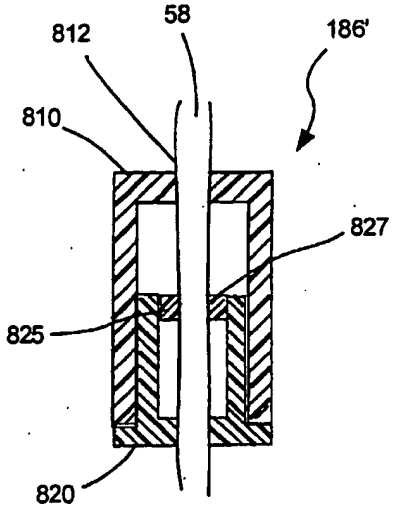

Fig. 11

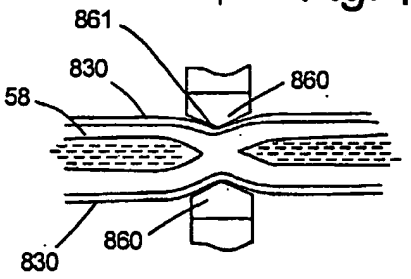

Fig. 12a

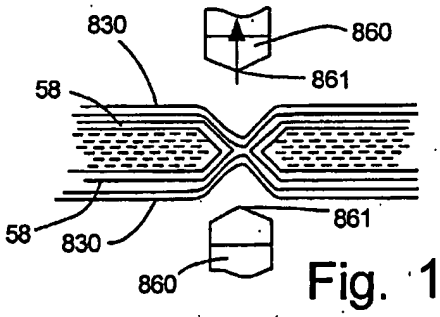

Fig. 12b

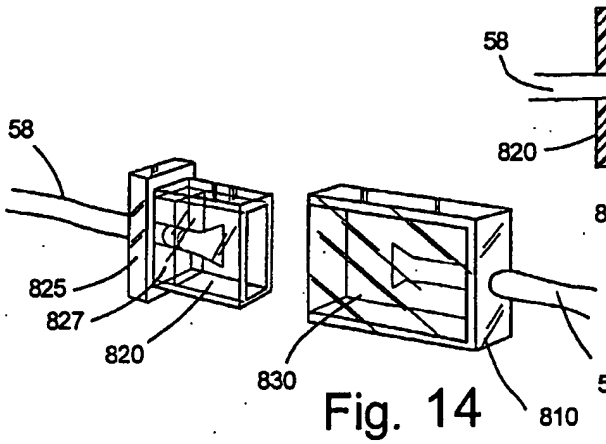

Fig. 14

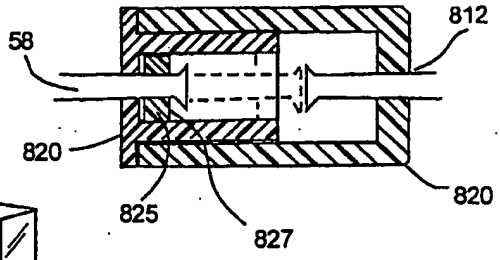

Fig. 13